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| APPLICATION NO.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,784                      | 04/08/2005  | Christoph Methfessel | 100717-660(KGB)     | 5735             |
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| NORRIS, MCLAUGHLIN & MARCUS, PA |             |                      |                     |                  |
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| EXAMINER                        |             |                      |                     |                  |
| LUM, LEON YUN BON               |             |                      |                     |                  |
| ART UNIT                        |             | PAPER NUMBER         |                     |                  |
| 1641                            |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/523,784

**Applicant(s)**

METHFESSEL ET AL.

**Examiner**

Leon Y. Lum

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date 2/9/05; 4/11/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicants' election with traverse of Group I, claims 11-17 and the species connexin and supported bilayer in the reply filed on June 30, 2008 is acknowledged. Although the election is made with traverse, Applicants have not presented any reasoning to support the traversal. Accordingly, the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 14 and 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species (claim 14) and group (claims 18-20), there being no allowable generic or linking claim. As stated above, Applicant timely traversed the restriction (election) requirement, although no arguments are provided.

### ***Information Disclosure Statement***

2. The information disclosure statement filed April 11, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. References AC (Hodgkin *et al.*), AD (Hodgkin *et al.*), AT (Brewer, G.J.) and AV (Allen, J.R.C.) have not been provided. The IDS has been placed in the application file, but the aforementioned references have not been considered.

3. The information disclosure statement filed February 9, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. References AG (Oh *et al.*), AH (Yamamoto *et al.*)

and AI (Postma *et al.*) have not been provided. The IDS has been placed in the application file, but the aforementioned references have not been considered.

#### ***Specification***

4. The disclosure is objected to because of the following informalities: there is no "Brief Description of Drawings" section in the specification referring to Figure 1 of the Drawings.

Appropriate correction is required.

#### ***Claim Objections***

5. Claim 16 is objected to because of the following informalities. The preamble recites "wherein the electrical signal is **at least one of.**" (emphasis added) Based on the preamble, elements a) through c) may all be present, or just one or two of the elements can be present. However, the term "and/or" in element b) renders the claim confusing. It appears that only "and" should be included. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 11-12 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazet *et al.* (Eur. J. Biochem., 210, 249-256 (1992)) ("Mazet") in view of Barbier *et al.* (US 2004/0126817) ("Barbier").

Mazet teaches a planar lipid-bilayer membrane stretched across a hole in a partition separating two chambers. See page 251, left column, last paragraph. The membrane comprises connexin-32, which is incorporated therein by contacting the membrane with a proteoliposome preparation comprising the protein. See page 252, left column, first full paragraph. Mazet, therefore, teaches "a membrane," as claimed. Mazet also teaches that channel activity attributed to connexin-32 can be detected by measuring current in response to voltage input. *Id.* at second full paragraph. Mazet, therefore, teaches "an electrical measuring instrument" and "electrodes" (claim 11) and the "providing" and "measuring" steps (claims 15 and 17), as claimed.

Mazet, however, does not teach a membrane body comprising at least one connexin or innexin.

Barbier teaches an assay to investigate gap junction intercellular communication, which includes contacting two embodiments comprising connexins. See page 2, paragraph 0010. In particular, Barbier discloses that the embodiments are cells. *Id.*

Given the teachings of Mazet and Barbier, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the arrangement of Mazet, described above, by including a cell comprising connexins. The modification would produce contact between the lipid bilayer comprising connexin-32 and the cell comprising connexins. As evidenced by Barbier, the skilled artisan would have been motivated to perform the modification since contacting the bilayer membrane with a cell comprising connexins would allow one to investigate intercellular communication. Moreover, the electrical measurements taught by Mazet would provide a different approach to investigating intercellular communication from the optical signal-approach of Barbier (see page 2, paragraph 0010). Furthermore, since the bilayer membrane of Mazet comprises connexin-32 and is capable of forming gap junctions, the skilled artisan would have had a reasonable expectation of success in combining the bilayer membrane with a cell that also comprises connexins and can form gap junctions.

Regarding claim 16, Mazet teaches the step of measuring current. See page 252, left column, second full paragraph.

Regarding claim 17, Barbier teaches the step of providing a test compound, in order to determine its affect on altering properties of the gap junction. See page 2, paragraph 0018-0019.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazet in view of Barbier, both cited above, as applied to claim 11 above, and further in view of Xu *et al.* (US 5,874,668) ("Xu").

The teachings of Mazet and Barbier are disclosed above. These references, however, do not teach a membrane that covers an end of a capillary as claimed.

Xu teaches a reconstituted membrane placed the end of a patch clamp electrode. See column 9, lines 35-39 and 54-65; and Figure 4D. This configuration allows one to understand adhesion forces between two surfaces and enables one to simultaneously image receptor structure and record single and multiple channel conductances. *Id.*

Given the teachings of Mazet, Barbier and Xu, one of ordinary skill in the art at the time of the invention would have found it obvious to place the connexin-32 incorporated membrane of Mazet and Barbier to the end of a patch clamp electrode. As evidenced by Xu, the skilled artisan would have been motivated to perform this modification since such an arrangement would allow one to understand adhesion forces between the bilayer membrane and cell, and also allow simultaneous measurements of single and multiple channel conductances. Moreover, since the patch clamp arrangement would allow the same type of conductance measurements taught by Mazet, the skilled artisan would have had a reasonable expectation of success in combining the teachings of Mazet and Barbier with the teachings of Xu.

### ***Conclusion***

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon Y. Lum/  
Examiner, Art Unit 1641

/Mark L. Shibuya, Ph.D./  
Supervisory Patent Examiner, Art Unit 1641